UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	)	

TRIAL OF CLASS 2 AND 3 CLAIMS

AFFIDAVIT OF LINDA A. HAEGELE, M.D.
SUBMITTED AS DIRECT TESTIMONY IN THE CASE-IN-CHIEF OF BRISTOL-MYERS SQUIBB CO. AND ONCOLOGY THERAPEUTICS NETWORK CORP. IN THE TRIAL OF CLASS 2 AND 3 CLAIMS

STATE OF PENNSLYVANIA)
) ss:
COUNTY OF PHILADELPHIA)

LINDA A. HAEGELE, M.D. being duly sworn, deposes and says:

1. I submit this affidavit on behalf of Bristol-Myers Squibb Co. ("BMS") and Oncology Therapeutic Network Corporation ("OTN") in *In re Pharmaceutical Industry Average Wholesale Price Litigation* to describe the professional customs and practices in the medical oncology field generally and office-based medical oncology specifically.

2. My affidavit is organized as follows: Section I discusses my qualifications, education and employment background. Section II provides an overview of the medical oncology sub-specialty and tracks its development from a hospital-based to an office-based practice. Section III discusses the benefits of office-based oncology care. Section IV details various aspects of my office-based practice and describes the

many services my practice provides to cancer patients. Section V explains the billing and reimbursement for office-based oncology care. Finally, Section VI analyzes the economics of my office-based practice from 2002-2005. In particular, this section discusses recent changes in Medicare reimbursement and their impact on my practice.

I. QUALIFICATIONS, EDUCATION AND EMPLOYMENT HISTORY

3. I am licensed to practice medicine in Pennsylvania and am board certified in Internal Medicine. I work full time as a medical oncologist in a solo private practice in Philadelphia called Physician Oncology, Ltd., where I treat various types of cancer and hematologic disorder patients. Breast cancer patients comprise 50% of my patients; 20% are lung cancer or colon cancer patients; and 30% of my patients have chronic leukemia or lymphoma, other malignancies or hematologic conditions. I see approximately 80-100 patients a week.

4. I am affiliated with and have staff privileges at several Philadelphia hospitals. Currently, I have staff privileges at Albert Einstein Medical Center, Einstein at Elkins Park, Temple University- Jeanes Hospital, Thomas Jefferson University Hospital, Temple University- Northeastern Hospital, and Nazareth Hospital. I am a member of the Pennsylvania Society of Hematology and Medical Oncology and the American Society of Clinical Oncologists.

5. I graduated *magna cum laude* from Temple University College of Liberal Arts in 1968. I obtained my medical degree from Temple University School of Medicine in 1973 and did my internship and residency in Internal Medicine at the Albert Einstein Medical Center, Northern Division, in Philadelphia from 1973-1976. After my residency, I was a Fellow in Hematology/Medical Oncology at Hahnemann University Hospital from 1976-1979. During my fellowship, I was an instructor in Hematology-Oncology and Course Director in Hematology in the School of Allied Health Professions.

6. From 1980 to 1997, I was Chairman of the Division of Hematology and Oncology and served as the Director of the Outpatient Infusion Unit, the outpatient chemotherapy unit at Parkview Hospital. During that period, I maintained staff privileges at other community-based hospitals in the Philadelphia area, including City Avenue Hospital and Episcopal Hospital where I served as Director of the Outpatient Infusion Units and was Chairman of the divisions of Hematology and Medical Oncology. I was also an active staff member at Albert Einstein Medical Center, Northeastern Hospital, Nazareth Hospital, Jeanes Hospital and Elkins Park Hospital. I was a member of the American Medical Association, the Philadelphia County Medical Society, the Pennsylvania State Medical Society, and the American College of Physicians from 1979-1997.

7. In addition to the practice of medical oncology and hematology, I have taught numerous courses in Hematology and Medical Oncology since 1980. I was Chairman of the Division of Hematology and Medical Oncology and Professor in the Department of Medicine at Philadelphia College of Osteopathic Medicine from 1990-2002. While at Philadelphia College of Osteopathic Medicine, I taught Interdisciplinary Oncology, a second-year student course, and Hematology/Medical Oncology, a third-year student clinical course. At Parkview Hospital, I gave lectures and made clinical rounds with medical residents and students of the Osteopathic school as Chairman of the Division of Hematology and Medical Oncology from 1980 until the hospital closed in 2003. At Episcopal Hospital, I instructed medical residents and Temple University medical students during my tenure as Chairman of the Division of Hematology and Medical Oncology from 1990-1997. At City Avenue Hospital, I taught medical residents as Course Director of Medical Resident Core Curriculum, Hematology and Medical Oncology from 1990 through 1997 and served as Chairman of the Division of Hematology and Medical Oncology from 1990 until the hospital closed in 2000.

8. I have held various committee appointments at Parkview Hospital, City Avenue Hospital, Temple University-Northeastern Hospital and Episcopal Hospital. I was a member of the Cancer Committee at Temple University-Northeastern Hospital

from 1991-1997. At City Avenue Hospital, I was Chairman of the Tumor Committee from 1990-1997. At Parkview Hospital, I was a member of the Tumor Committee from 1979-1982; Chairman of the Tumor Committee from 1982-2003; member of the Formulary Committee from 1985-2000; member of the Medical Education Committee from 1991-2000; and Medical Oncology Advisor for the patient Cancer Support Group from 1980-1997.

9. In July 1997, I began treating patients in a private infusion center owned by Physician Oncology Specialists, Inc. The company was owned and operated by Comprehensive Cancer Centers, Inc., a subsidiary of Salick Health Care, Inc. I was salaried as the medical oncologist/hematologist for the company's new facility in the Northeast Philadelphia area.

10. In July 1999, I bought the facility after Salick Health Care, Inc. decided to leave the Philadelphia market. Apparently, after several years in the Philadelphia area, the corporation determined that their total operations were not adequately profitable to warrant further development.

11. A more complete description of my qualifications and employment background can be found in my *Curriculum Vitae*, attached as Appendix A to this affidavit.

12. I have had no relationship with any pharmaceutical companies other than my retention by their counsel in this matter, participation on some advisory boards, and a consulting agreement I had with Novartis that was effective June 1, 2003 to May 31, 2004. Novartis agreed to pay me $150 per hour to consult on the use of such Novartis drug products as Zometa, Femara, Gleevec and Sandostatin LAR Depot. Although I signed the consulting agreement with Novartis, I did little consulting work. It is my understanding that Novartis decided to work with a smaller group of oncologists, which I was not part of.

13. On occasion, I have been compensated by various pharmaceutical companies for my participation on their advisory boards. The pharmaceutical companies that sponsor these advisory boards seek information on the clinical efficacy and use of their new chemotherapy drugs from practicing oncologists. I participated on various advisory boards about once or twice a year. Joining an advisory board allows me to provide feedback about a new drug and its side-effects to that drug's manufacturer. I am paid a stipend of $500-$1,000 and reimbursed for my travel and hotel expenses.

14. I was introduced to counsel for BMS and OTN through a group meeting of oncologists in Philadelphia in 2005.

15. My rate of compensation in this matter is $300 per hour.

II. OVERVIEW OF MEDICAL ONCOLOGY SUB-SPECIALTY AND ITS DEVELOPMENT

16. Within the oncology specialty, there are 3 sub-specialties: surgical oncology, radiation oncology, and medical oncology. Surgical oncologists are surgeons with specialized experience and training in the treatment of cancer, including biopsy techniques to obtain adequate tissue to establish a tissue diagnosis, resection of malignant cancers, and surgical staging. Radiation oncologists utilize various radiation techniques to treat malignancies. Medical oncologists are physicians with training in internal medicine, and subsequently in the sub-specialty of medical oncology and hematology.

Medical oncologists often facilitate necessary "staging" procedures (by which cancers are diagnosed and described) and assist in coordinating care with other sub-specialists. The primary treatment role of the medical oncologist is to determine the most effective and most tolerable regimen of drugs to treat a patient's particular type and stage of cancer. Today, medical oncologists also facilitate palliative care for terminally ill cancer patients.

17. The American Board of Internal Medicine did not recognize medical oncology as a sub-specialty until June 1972, and the first certifying examination in medical oncology did not take place until October 1973.

18. During my fellowship, in the late 1970s, chemotherapy was frequently a supplemental treatment given in addition to the primary treatment of surgery and/or radiation. There were few chemotherapy drugs and the drugs were often administered as a single agent, not in combination with other drugs. It was not until the late 1970s that the drugs commonly became administered in recognized groups called a drug "regimen." A regimen is a treatment course where several oncology drugs are administered in combination. The optimal chemotherapy regimen combines drugs which are effective at combating the tumor via different biological mechanisms – and thus exhibit combined efficacy on the tumor— without additive toxicities.

19. In the 1970s, most chemotherapy was administered in the hospital setting. The patients often had surgery or other treatment requiring hospitalization, and the chemotherapy itself required long infusion times for safe administration. Patients often needed hospitalization to treat frequent debilitating side-effects caused by the cytotoxic chemotherapy: nausea and vomiting with dehydration, anemia, low white blood cell count (neutropenia) and subsequent infection, and cardiac, pulmonary or renal toxicity.

20. In the 1980s and 1990s, as medical oncologists' knowledge of chemotherapy progressed, and with the advent of new chemotherapy drugs and novel supportive care medications, both the uses of chemotherapy and the sites of patient care expanded – first to hospital based outpatient clinics and later to physician offices. Administration of chemotherapy – in a regimen with multiple drugs that have less overlapping toxicity – was increased when compared to older (or previous) courses of larger doses of cytotoxic drugs.

21. The advent of better drugs to prevent nausea (anti-emetic drugs) and growth factors which reduce neutropenia and anemia, have enhanced the ability of

physicians to provide chemotherapy in an office-based oncology practice. With appropriate pre- and post-chemotherapy anti-emetic drug administration, patients may receive potent cytotoxic drugs without experiencing nausea, vomiting or attendant dehydration, which frequently precipitated hospitalization for intravenous re-hydration of patients in the past. Growth factors administered in combination with myelosuppressive drugs (agents which lower the white blood cell count) enable patients to maintain adequate white blood cell counts and avoid potentially life-threatening infections. Synthetic erythropoietin, which stimulates the bone marrow's production of red blood cells, can reduce the development of anemia and enable patients to avoid blood transfusions.

22. Today, in addition to adjuvant chemotherapy (given after surgery or radiation) and palliative chemotherapy (drug therapy administered to patients with metastatic cancer to prolong their lives and improve their quality of life by minimizing the symptoms caused by cancer), there is now neoadjuvant chemotherapy – therapy administered prior to the surgical removal of the cancer to shrink the cancer mass, often enabling surgical oncologists to resect tumors which previously had been too large to be removed with current surgical techniques. New treatment regimens, advances in cytotoxic drug regimens, and better supportive care drugs accelerated the movement of chemotherapy from hospital in-patient treatment to hospital outpatient facilities and later to physician offices. This evolution of care has benefited the patient, the medical oncologist providing care, Medicare and the insurance providers.

III. BENEFITS OF OFFICE-BASED CARE

Patient Quality of Care

23. My own professional career has followed the trajectory of medical oncology from a hospital-based practice to an office-based one. The prime reason I moved my practice from the community hospital outpatient units to a private oncology office in 1997 was to provide better care for my patients. My patients receive better medical care in an office-based environment where they interact with the same staff and

nurses and develop a rapport with these people during the course of their treatment. I cannot emphasize enough how the personal aspects of office-based treatment are better for the patient than the regimentation of the institutional setting of a hospital or a hospital's outpatient clinic.

24. In a private office infusion setting, the patients receive therapy more efficiently than if they were treated in the hospital or at an outpatient clinic. Much of the time required to administer the chemotherapy treatment involves delays in obtaining the results of laboratory tests on the patient's blood to check his progress and the mixing and infusion of the patient's drugs by the pharmacist or nurse. Because I have my own laboratory onsite, my patients do not have to wait as long to obtain their blood count results as they would in a hospital outpatient clinic. In the hospital, my experience has been that the lab technician performs tests and the pharmacist mixes drugs for hospitalized patients first, delaying delivery of the outpatient chemotherapy results and drugs to the infusion unit and prolonging the duration of therapy. At my oncology office, the patient does not wait as long because my nurse mixes the drugs under the laminar flow hood after I have reviewed the patient's blood count.[1] The nurse then infuses the IV fluids and drugs including the anti-emetic agents while the patient sits in the infusion chair. Depending on the regimen utilized, the patient can be out of my office in four to five hours or less.

The Benefits to the Insurer

25. Regardless of the site of patient care – a hospital, an outpatient clinic or a physician's office – certain clinical practices, physical plant requirements and personnel staffing are essential for effective diagnosis and treatment of patients who require chemotherapy. For example, the medical provider must obtain the necessary drugs, have a venue to evaluate patients and to administer therapy, and employ medical and clerical

[1] A laminar flow hood, also known as a biological safety cabinet, removes contaminants in the air. It takes in room air and passes the air through a pre-filter which removes lint, dust and other large particles. The laminar flow hood then compresses the air and channels it through a HEPA (high efficiency particulate air) filter which removes nearly all bacteria. The purified air flows out at a uniform velocity over the entire work surface below the hood. The constant flow of purified air over the work area prevents room air from entering and contaminating the mixed chemicals for infusion into patients.

support staff. To continue operation, it is essential for the practice to achieve a profitable financial return for the time and expertise of the personnel, the drugs and other materials employed and the treatment center space utilized to provide care. This reimbursement must be the responsibility of the patient and/or insurer. I believe that office-based treatment for oncology patients is much more cost effective than other models of patient care.

26. Since I have practiced as a medical oncologist in hospital, outpatient and office settings, I am generally familiar with the practices, physical plant and personnel of each. Although I have not worked in hospital administration and therefore am not qualified to give a detailed opinion on the relative costs of delivering chemotherapy on an inpatient or outpatient hospital facility, I believe that it is more expensive to provide cancer treatment in a hospital due to the exorbitant institutional overhead costs. It is extremely expensive for a hospital to maintain a fully-equipped and staffed laboratory, pharmacy, and physical plant. The nurses employed by a hospital are usually full-time employees who require extensive salaries and benefits, while the nurses working in my practice are per diem employees.

27. I also believe that the cost of oncology patient care is higher in the hospital outpatient setting than in the office setting. In recent statements made to the Medicare Payment Advisory Commission, which advises government policy makers, Dr. Joan Sokolovsky, a MedPAC staff member, confirmed this. Dr. Sokolovsky reported that she had learned from private payors and health plans that it costs them two to three times as much when a patient is treated in the hospital outpatient department than in a physician's office. Statement of Joan Sokolovsky, Medicare Payment Advisory Commission Public Hearing, at 223 (Sept. 8, 2005).

The Benefits to the Practitioner

28. Not only does office-based practice offer the medical oncologist the professional satisfaction of providing care to patients in a more intimate and efficient setting than in a hospital or clinic, it offers the physician the financial opportunities of

managing the practice as a business. The financial incentives must be sufficient to cover the expenses of building space and equipment, personnel salaries and benefits for reception, nursing and laboratory staff, and of maintaining adequate inventories of expensive chemotherapy and supportive care drugs.

29. In the next section, I provide in detail a description of how my practice functions on a daily basis to illustrate how much time, expertise and materials are necessary to run an office-based oncology practice. I will show that, historically, it has been the profit or margin that I have collected on the drugs administered to the patients that has allowed my office to exist. This is because insurers have not compensated my private practice for many of the services which are provided to the patients during their course of treatment.

IV. The Practice of Office-Based Oncology

30. *Physical Plant*: My office is located at 9600 Roosevelt Boulevard, Suite 301, Philadelphia, PA 19115. I lease approximately 2,800 square feet of space. The space consists of a waiting room, a medical records room, an infusion room where patients receive treatment, a pharmacy room with a laminar flow hood, a storage room, a laboratory room, a utility room, a lunchroom/conference room, four examination rooms, and four offices for secretarial and billing staff and for myself. The nurses administer chemotherapy in the infusion room, which currently has eight infusion chairs. The nurses mix the drugs under the laminar flow hood in the pharmacy room. The hood is inspected every August to insure compliance with the Occupational Safety & Health Administration (OSHA) requirements to insure appropriate safety during drug reconstitution. The storage room contains patient literature, including nutritional materials and cancer information pamphlets, IV fluids and needles, and other medical supplies. Biohazard waste containers are kept in the utility room and the waste is disposed of once a month by a private company.

31. *Staff*: I currently employ three staff members in my private practice. I have a full-time receptionist, a full-time assistant biller/receptionist and a full-time clinical assistant/lab assistant. In January 2006, my full-time biller left for a job closer to her house. She is working part-time with my practice to assist me with billing. In addition, I employ several oncology nurses on a per diem basis. I also utilize a laboratory technician consultant on an hourly, as-needed basis. I presently do not have a practice manager, but utilize a consultant on an hourly basis to assist me in managing my practice. My typist works on a per-hour basis to transcribe the letters which I dictate and send to the patient's primary care physician, surgical oncologist, pulmonologist, cardiologist or any other specialists participating in a patient's care. The time I devote to the letters that I send to other physicians, detailing my medical assessment and treatment plan, are an important part of my clinical practice since my findings are essential in coordinating the patient's care with the other specialists. Unfortunately, I am not reimbursed for my time and expenses in writing or sending these letters, including my typist's salary.

32. *Drugs and Supplies*: I order drugs and supplies about once a week from OTN, a specialty distributor. When the drugs arrive, they are stored in cabinets or in the refrigerator in the pharmacy room. My weekly bills for pharmaceutical agents and supplies were approximately $20,000-$60,000 between 2002-2005. However, it may take weeks or months before I am reimbursed for this financial outlay. While payors reimburse for the drugs, they usually do not reimburse me for the supplies needed to administer the drugs.

33. *Pre-Visit Clearance of Patients*: Before a patient visits my office, my receptionist obtains preliminary demographic, insurance, and medical information. She obtains the patient's medical file from the referring surgical oncologist, primary care physician or other referring physician. Once the patient arrives at the office, my receptionist requests the patient to complete personal information forms including the patient's insurance information, the necessary referrals and the co-pays. If the referral has expired, she assists the patient in obtaining a new referral. I cannot evaluate or treat a patient if that patient has an expired referral because the insurance company will not

reimburse me for the medical care. If the referral indicates "evaluate only," I can only evaluate the patient. I cannot proceed with studies or treatment. If the referral says evaluate and treat, my office personnel may perform laboratory tests and I can proceed with treatment. My receptionist's services are not reimbursed by Medicare or any of the commercial payors.

34. *Initial Consult and Physical Examination*: After the patient fills out the releases and forms, the patient waits in the waiting room for the scheduled appointment. I have candies by the reception desk and cookies, water, sodas and juices in the waiting room for patients and their escorts, since clinical evaluations and appointments may require prolonged visits. I typically spend $900 a month on refreshments for my patients.

When I am ready for the patient's visit, my clinical assistant takes the patient to an examination room and records the patient's height, weight, blood pressure, temperature, pulse and respiration. I then meet with the patient and also with her support person. I do not have clocks in any of the examination rooms because I do not wish to feel restrained in devoting the necessary time with each patient. Typically, I first ask the patient to describe an actual symptom.[2]

Next, I obtain a detailed clinical history of each new patient, and an interim history for established patients who are returning for evaluation. The initial history includes the patient's chief complaint, the primary reason that the patient has come for evaluation by me, a medical oncologist-hematologist. This may be a particular symptom which the patient is experiencing, an abnormal test result which has prompted the referring doctor to request a consultation with me, or a newly established diagnosis of a cancer or a blood problem which requires further evaluation and treatment. The history of the patient's present illness provides further details of this initial problem. I also obtain other details of the patient's history, including occupational history and possible toxic exposures, social history, including family and home support resources, tobacco and alcohol use, diet and nutrition, current medications, family medical history and the

[2] Some patients may be in pain, or feel weakness and fatigue; others simply tell me they are seeing me because they were referred by their primary care physician or surgeon. Next, I ask the patient about her present history. Some patients have had surgery to remove a tumor and are seeing me after their operation. Other patients are referred by their primary care physician after the X-ray reports and biopsy results show they have cancer. I base my treatment plan in part on the patient's answers to these questions.

patient's prior medical history. In addition, I perform a careful review of the patient's body systems, which include specific questions relating to the basic organ systems (for example, the gastro-intestinal tract, lungs or cardiovascular system).

After completing my detailed interview with the patient and reviewing the data provided by the referring physician, I proceed with a thorough physical examination of the patient. This includes specific evaluation of the head, ears, eyes, nose and throat; lymph node sites; chest, including the chest wall, lungs and heart; abdomen; extremities and nervous system.

35. *Taking Blood and Lab Tests*: After I see the patient, my clinical assistant draws the patient's blood using sterile technique with butterfly needles and tubing. She performs a complete blood count in the laboratory and submits appropriate blood specimens to the outside laboratory for specialized studies if ordered by me. I also employ a registered laboratory technician who works on an as-needed basis as a consultant to ensure laboratory quality control. I maintain a state license to operate the laboratory and as the director of the laboratory, I supervise my clinical assistant and review the laboratory results with her and the nurses. The supplies, equipment, credentialing, and supervision of the laboratory is not reimbursed by Medicare or the health plans. I lose money operating the laboratory for my office but I feel it is imperative to have the capability of obtaining a complete blood count for patients on the premises to facilitate treatment decisions.

36. *Cognitive Services*: After the physical examination and review of test results, I proceed to stage the patient's tumor or disease to determine its extent using the Clinical TNM Classification and Staging form created jointly by the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC). For instance, for patients with a solid tumor like breast cancer, I evaluate the tumor size in the breast, the possible involvement of the regional lymph nodes by tumor, and whether the cancer has metastasized to other parts of the body. In the TNM system, TNM stands for Tumor, Nodes, and Metastases, in which the T category describes the size of the original (primary) tumor and/or the level of invasion into regional areas, the N category describes

whether or not the cancer has reached regional lymph nodes, and the M category describes whether the cancer has spread to other parts of body. The T, N, and M status is often correlated with an overall stage of I, II, III, or IV.

37. *Treatment Plan*: I develop the treatment plan based on the primary cancer type, the stage of the cancer and my risk assessment of the patient's present and past illnesses, current medication, past medical history, allergies, and ancillary factors, such as alcohol consumption or smoking. For instance, I cannot utilize certain drugs for cancer treatment if the patient's liver is compromised as a result of alcoholism or if the patient has kidney disease. Similarly, if the patient has a heart condition, a drug which potentially aggravates the condition because of its side effect of cardiac toxicity is not safe. If the patient has severe asthma, Taxotere may exacerbate this and preclude the drug's use, even though a patient with breast cancer might benefit from a regimen of Taxotere, Adriamycin, and Cytoxan ("TAC regimen").[3] Multiple aspects of the patient's medical history or co-morbid conditions may influence final recommendations for chemotherapy to combat a patient's malignancy.

I initially prepare chemotherapy orders following established drug dosages and appropriate regimens, according to the patient's individual height and weight, first ascertaining that the prescribed drug combination is recognized by the patient's insurance or Medicare and that the drugs will be paid by the payor.

After I clinically evaluate the patient and review his blood count, I confirm the specific drug dosage. Prior to the patient's initial treatment appointment, the nurse has ordered the necessary chemotherapy agents, anti-nausea and other supportive care drugs, and medical supplies, including needles, IV tubing and sterile solutions. I confirm the specific drug dosage and the nurse then proceeds to obtain IV access for the patient, mixes and administers supportive care drugs, and then prepares the IV chemotherapy drugs under the laminar flow hood, utilizing OSHA-approved gloves and gown. The nurse then administers the drugs according to prescribed protocol. During

[3] Although I refer to the TAC regimen by using the brand name of the innovator drug for doxorubicin HCL (Adriamycin) and for cyclophosamide (Cytoxan), I generally prescribe the generic equivalents of these drugs.

drug administration and prior to completion of the visit, the nurse provides additional instructional information for the patient and his support person.

My office does not obtain reimbursement for my nurses' time spent ordering the drugs, mixing and preparing the supportive care drugs and chemotherapy drugs, or educating and counseling patients and their families on the side-effects of the drugs and on good nutrition. Moreover, medical supplies such as gloves, gowns, needles, IV tubing and sterile solutions used to mix the infusion drugs are not separately reimbursed by Medicare or the private payors.

38. *Infusion*: Once I have determined a specific treatment plan for a patient, it is necessary to implement it. This requires taking the drugs out of inventory and mixing them with appropriate sterile solutions under the laminar flow hood, after the dose is confirmed after review of the patient's complete blood count. Other supplies are used in connection with drug infusions including bandages, syringes, saline solution, needles, and IV tubing. For example, the Taxotere, Adriamycin, Cytoxan (TAC) regimen utilized as adjuvant chemotherapy for breast cancer patients requires the administration of pre-therapy medications including anti-emetics and antihistamines such as Benadryl and cimetidine. The patient is then infused with Adriamycin and Cytoxan followed by an hour delay before the third agent, Taxotere, may be infused. The next day, the patient visits the office and receives growth factors, Neulasta to increase her white blood cells and Aranesp to increase her red blood cells, to minimize two common side effects of chemotherapy, neutropenia and anemia. The TAC regimen is given once every three weeks for a total of six treatments. While the nurse administers the chemotherapy regimen, she educates the patient on the possible side effects of the drugs. During the infusion, I am on site to supervise the nurse and deal with any allergic reaction or immediate side effect from the infused drugs. If and when the patient develops a reaction to the drug, the nurse stops the infusion of the cytotoxic chemotherapy and administers other drugs to counter the reaction. Patients are instructed to notify me at any time if they have a question or suspect a reaction to treatment. Multiple aspects of such care remain unreimbursed; this includes the instructional/counseling time of the nurses, all of the

tubing and needles necessary to administer the drugs and the physician and/or nurse time responding to subsequent patient telephone calls.

39. *Counseling*: Beginning with the initial office visit, I provide counseling to the patient and his support person. I inform the patient about the disease, the treatment plan and implications regarding response, and review the side effects of the chemotherapy regimen. Cancer is a catastrophic disease and takes an emotional toll on the patient and the family. I advise the patient and family members about disease management and provide emotional support during the office visit as well as in subsequent phone calls. My calls to the patient and family members are not reimbursed by Medicare or the commercial payors. Although my practice is too small to have a social worker on staff as in the hospitals and larger oncology clinics, my receptionist provides necessary services to patients. She makes transportation arrangements for the patient, coordinates the patient's appointment with other specialists such as the surgical oncologist or radiation oncologist, calls the nursing agency for a home nurse for the patient if he needs home care, calls the hospice if the patient needs hospice care, and assists the patient with the patient assistance form if the self-administered drugs or oral chemotherapy drugs I prescribe are not on a health plan's formulary and the patient cannot pay for the drugs. This is in addition to my receptionist's other responsibilities which include verification of insurance coverage for the patient's therapy and any other additional services. She spends approximately four hours a day assisting patients in these matters. None of these services are reimbursed by Medicare or any of the commercial payors.

We also educate the patient about the importance of good nutrition. Clinical studies show that patients who have better nutrition can tolerate the chemotherapy drugs better. It is important to ensure that the patient has a good diet because the tumor often causes anorexia, weight loss (cachexia) and some patients lose their taste for some foods because of the drugs they are taking. I provide the patient with samples of nutritional products such as Ensure or Glucerna (a nutritional drink for diabetics) and nutritional information books provided by several drug manufacturers.

Although my practice does not have a nutritionist, I am aware that larger oncology offices and hospitals may have a nutritionist on staff.

In addition to the counseling that my receptionist, the nurses, and I provide when we see the patient during an office visit, my office also organizes a cancer patient support group for women with breast cancer that meets every two months in the office. The support group allows patients to share their experiences with each other and to provide emotional support to each other. I provide refreshments during the meetings and occasionally, a drug manufacturer sales representative will provide refreshments for the group. While the support group facilitates the patients' healing process, my work with the support group is not reimbursed by any payor.

40. *Evaluation of and Changes to Treatment*: A course of treatment whether the regimen is for neoadjuvant, adjuvant or metastatic chemotherapy requires follow-up visits by the patient. Each time the patient visits my office for chemotherapy, I review all symptoms, counsel the patient about side effects and nutrition, and conduct a physical examination. Before chemotherapy is administered, the clinical assistant performs the blood count tests to ascertain whether the patient's complete blood count is adequate to proceed with treatment that day.

If the patient cannot be given chemotherapy that day, my receptionist schedules an appointment for another day. If the patient cannot tolerate the side effects of a particular drug regimen or if studies indicate disease progression, modifications are made in the particular drug regimen or an alternative drug regimen is prescribed and administered after extensive discussion with the patient and caregivers.

On occasion, new clinical data influences the patient's course of treatment. For example, Herceptin is a monoclonal antibody that is FDA-approved for treatment of metastatic breast cancer to block the HER2 protein in cancer cells and stop the growth of HER2-positive cancer cells. About one out of every four breast cancers is HER2-positive and this probably represents a more aggressive tumor than HER2-negative breast cancers. Since remarkable clinical data discussed in a 2005 ASCO meeting demonstrated

Herceptin's efficacy in the adjuvant setting, I am currently utilizing Herceptin as adjuvant chemotherapy for HER2/Nu+ breast cancer patients.

41. *Patient Advocacy*: Frequently, it is necessary to obtain approval or pre-certification from the patient's insurance before proceeding to administer specific therapy. This process often entails prolonged telephone contact with the carrier, before therapy care be initiated. For example, before I prescribe Herceptin to a patient, I ascertain that the health plan will reimburse me since Herceptin is a patented single-source drug which is very expensive. Fortunately, the health plans are reimbursing Herceptin for off-label use because the patient advocacy groups have publicized Herceptin's effectiveness as adjuvant chemotherapy and the scientific/clinical data is now established. The time spent by me and my staff obtaining such insurance approval is never reimbursed.

V. BILLING AND REIMBURSEMENT FOR OFFICE-BASED ONCOLOGY

42. In the previous section, I have outlined some, but not all, of the time, expertise and expense it takes to run my medical oncology practice – with special emphasis on that which is not compensated by payors. In this section, I discuss the goods and services that are compensated by the public and private payors with whom I work.

43. At the outset, I must state that billing and reimbursement for medical oncology is very bureaucratic, arcane and complex in both the public and private sphere. Very generally, I am reimbursed for (1) office visits; (2) blood tests; (3) the service of administering drugs and (4) the drugs themselves. As I will show, the reimbursement amounts for the first three have historically been so low that, had I not derived significant revenue from the drugs themselves, it would not have been economically feasible for me to provide office-based chemotherapy.

44. My office accepts reimbursement from Medicare and from various private payors. Twenty percent of my patients have coverage through Medicare Part B or Part C

(the Medicare Advantage HMOs known as Health Partners Senior Partners and Elder Health). Most of my Medicare Part B patients have Medigap coverage through United Healthcare or Blue Cross/Blue Shield. Another 10% of my patients have a Medicaid HMO plan through Keystone Mercy Health Plan (operated by Independent Blue Cross) or AmeriChoice.[4] The remainder of my patients have private health insurance: 30% have coverage through Preferred Provider Organization ("PPO") plans including Personal Choice from Independence Blue Cross, Aetna US Health Care and Pennsylvania Blue Shield; another 30% have coverage through Health Management Organization ("HMO") plans including Aetna US Health Care, Keystone Health Plan East (operated by Independent Blue Cross), Amerihealth and Cigna; and another 10% have a commercial insurance plan through, among others, United Health Care and UFCW Local 56 Fund.

Being a sole practitioner in a metropolitan area, I have little ability to negotiate with the commercial payors. They dictate the terms of the contract and I can agree to their terms or not participate in their networks. Finally, especially with commercial insurance, my patients have some obligation to pay either a fixed or percentage co-payment. At the end of this section, I relate my experience in trying to collect these co-payments.

45. My office bills Medicare using the HCFA Common Procedure Coding System (HCPCS). The HCPCS codes have been adopted by the private payors so we bill the health plans using the same coding system as Medicare.

46. HCPCS comprises three types of codes, only two of which are relevant to my office. HCPCS Level I codes are Current Procedural Terminology (CPT) codes, developed and updated annually by the American Medical Association. These CPT Codes generally correspond to medical procedures and are broken down by categories

[4] I believe that I am the only office-based oncologist in the Northeast Philadelphia area that will accept these Medicaid HMO patients because the reimbursement allowances for them are so poor compared to those by Medicare and other commercial payors. Other than the two Medicaid HMO plans described above, even I do not accept Medicaid patients because I would lose money if I treated them. If the patient has a Pennsylvania Medicaid Access card, I send that patient to Temple Hospital, a state-related institution, because I cannot afford to provide care for that patient.

based on medical specialties.[5] HCPCS Level II codes begin with a single letter (A-V) followed by four numeric digits and are used to identify products, supplies, and services not included in the CPT codes. For medical oncology, the relevant HCPCS Level II Code is the "J-Code," which is for the drugs that are administered to the patients.

47. *CPT Codes- Office Visit and Consultations*: For medical oncology, the office visits are billed using the Evaluation and Management or "E/M" CPT Codes. The E/M CPT codes describe the office visits and consultations, which must be face-to-face; I cannot bill for the hours I spend with patients over the telephone or on my own with their insurers or other family members.

There are five CPT codes for an initial office consultation (CPT Codes 99241 to 99245, often referred to as Level I-V). I bill my E/M services as an initial consultation (CPT Codes 99241 to 99245) if the patient is referred to me by another physician who requests my advice or opinion about the diagnostic and/or treatment options. In my practice, the Code for an initial visit is usually 99245 or Level V, because it requires comprehensive documentation of the patient's history, a multi-system physical examination, a complex diagnosis and evaluation of various treatment and pain management options and/or referrals to other specialists. I usually spend at least an hour with the patient. Afterward, I create a written report of my findings and recommendations. The written report must be sent to the referring physician.

Medicare and the private payors below have reimbursed my practice the following amounts for a Level V initial office visit (CPT Code 99245) from 2002-2005:

[5] The CPT codes are divided into six sections: Evaluation and Management (E/M) (CPT Codes 99201-99499); Anesthesia (CPT Codes 00100-01999); Surgery (CPT Codes 10040-69999); Radiology (CPT Codes 70010-79999); Pathology and Laboratory (CPT Codes 80002-89399) and Medicine (CPT Codes 90700-99199). The Level III HCPCS codes, not used by my office, are local codes assigned and maintained by the individual state Medicare carriers to describe new procedures and services not listed under Level I and II codes. These codes begin with a single letter (W-X) followed by four numeric digits.

	Reimbursement Amount for Level V Initial Office Visit			
Provider	**2002**	**2003**	**2004**	**2005**
Medicare	$193.26	$193.26	$222.23	$225.81
Aetna	$ 100.00	$100.00	$194.00	$194.00
Health Partners of Philadelphia	$53.41	$53.41	$59.82	N/A
Independence Blue Cross	$120.00	$120.00	$160.00	$160.00

In 2004 and 2005, Medicare, Aetna, Independence Blue Cross, and Health Partners of Philadelphia increased their reimbursement for the Level V initial office visits.

Subsequent office visits are billed under Codes 99211-99215, which again reflect the differing levels of E/M services provided and which for billing purposes must be fully documented in the patient's records. I generally bill these subsequent visits as a Level III (CPT code 99213), Level IV (CPT Code 99214) or Level V (CPT Code 99215) E/M services. The most frequent Code billed is a Level V established patient visit (CPT Code 99215).

Medicare and some of the private payors have reimbursed my practice the following amounts for a Level V established patient visit (CPT Code 99215):

	Reimbursement Amount for Level V Established Patient Visit			
Provider	**2002**	**2003**	**2004**	**2005**
Medicare	$102.87	$102.87	$120.10	$121.17
Aetna	$ 50.00	$50.00	$105.00	$105.00
Health Partners of Philadelphia	$97.27	$112.27	$62.57	$62.57
Independence Blue Cross	$74.00	$74.00	$86.00	$86.00

Medicare, Aetna and Independence Blue Cross increased their payment for the Level V established patient visits in 2004 and 2005. Health Partners of Philadelphia decreased its reimbursement in 2004 and 2005.

I view the 2002-2003 reimbursement amounts for initial and subsequent office visits as highly inadequate if divorced from money I also received from buying and billing for the drugs provided to my patients. I often spend more than an hour with the patient on the initial visit. While there is, theoretically, a CPT Code for an "extended"

visit, both Medicare and the private payors make the required forms for qualification so onerous and difficult to satisfy that, as a practical matter, I am better off writing off my time rather than trying to qualify. It is my understanding from discussions with other medical oncologists that they also do not bill using the extended CPT code because of the burdensome documentation requirements. Further, as noted above, I am not compensated at all for the time I spend on the phone counseling my patients and their families or coordinating care with other physicians. Finally, the low reimbursements for office visits do not adequately compensate my office for my staff's time arranging the visits, assisting the patients during the visits and the paperwork of processing my reports and bills.

In 2004 and 2005, Medicare and most private payors increased their reimbursement for office visits. Medicare raised its reimbursement rate for office visits at the same time it lowered reimbursement for drugs in 2004.

48. *CPT Codes-Laboratory*: My office used CPT Codes 85023[6] and 85025 to bill Medicare and private payors for performing the complete blood count lab work. My office has an on-site lab because I need to determine the patient's white blood, hemoglobin and platelets counts before my nurses can administer chemotherapy. Medicare and the private payors pay me very little for the lab work.

For the complete blood count lab work (CPT Codes 85023 and 85025), my office was paid the following fees from 2002-2005:

	Reimbursement Amount for Blood Count Lab Work			
Provider	**2002**	**2003**	**2004**	**2005**
Medicare	$11.71	$10.74	$10.86	$10.86
Aetna	$13.00	$9.00	$7.00	$7.00
Health Partners of Philadelphia	N/A	$10.74	$6.54	$6.54
Independence Blue Cross	$9.00	$9.00	$9.30	$9.30

[6] CPT Code 85023 was deleted effective January 1, 2003 and replaced with CPT Code 85025 to describe the complete blood count test. At that time, some private payors allowed my office some leeway. They reimbursed under CPT Code 85023 up to six months after its deletion. Beginning in January 2006, the private payors no longer provide this leeway; a failure to bill under the proper code will lead to a denial of the claim.

In addition, for the blood draw to do the blood count, Medicare paid $3 under CPT Code 36415 (collection of venous blood by venipuncture). The health plans also reimbursed my office $3 for the blood draw.

Given the low reimbursements, I lose money operating the lab. The lab reimbursement does not adequately reimburse me for the lab assistant's time drawing the blood, running the tests and analyzing the results, my supervision time, the cost of renting the Beckman-Coulter blood analyzer ($877 per month), maintaining the state license (about $300 per year) and the necessary supplies such as bandages, swabs, gloves, gowns, tubing and test tubes.

49. *CPT Codes- Administration of Drugs*: My office bills Medicare and private payors using several drug administration codes. Prior to January 1, 2005, administration of drugs was billed using CPT codes.[7] The *infusion* of saline (for hydration), antiemetics (to reduce nausea), diuretics (to reduce bloating), or any other supportive care drug was billed using CPT Codes 90780 to 90781 (therapeutic or diagnostic infusions). Billing for *injection* of supportive drugs is based upon whether the agent is a subcutaneous or intramuscular injection (CPT Code 90782), an intra-arterial injection (CPT Code 97083) or an intravenous injection (CPT Code 90784). Administration of the chemotherapy agents themselves was billed using CPT Codes 96400 to 965425. These various CPT codes for chemotherapy administration again correspond with the method used to administer or deliver the drug to the patient, i.e. whether it was administered by *injection*, *infusion* or *IV push* and whether it is was administered in the first hour of a patient treatment session or in a later hour.[8]

[7] In 2005, the Centers for Medicare & Medicaid Services (CMS) replaced the drug administration CPT codes with G codes. CMS added several new G codes that described the administration of additional sequential drugs. These new codes acknowledge the additional work and practice expense associated with the provision of multiple drugs.

[8] There are three methods to administer the drugs: injection, IV push and infusion. An injection is a dose of drug injected into the body with a syringe by a nurse or physician. If the injection is administered through the skin (subcutaneous injection), the drug is sequestered in a localized area, being forced into the interstitial fluid that surrounds the local cells and capillaries. The drug will enter the bloodstream via these local capillaries. Because of the limited physical dispersion of the drug dosage, the absorption of drugs administered subcutaneously tends to be slow and uniform. Some drugs have irritant or caustic effects upon local tissues that will cause the skin to slough off if administered subcutaneously. These problems can be minimized by administering the drugs deeply into the muscle mass (intramuscular injection). Other

In 2002 and 2003, the amounts allowed by Medicare and the private payors for the drug administration codes my office most heavily utilized were as follows:

Code	Description	Year	Medicare	Aetna	Health Partners of Philadelphia	Independence Blue Cross
90780	IV infusion for therapy/ diagnosis; up to one hour	2002	$42.72	$45.00	$41.11	$38.00
		2003	$42.72	$43.00	$41.11	$38.00
90781	IV infusion therapy/ diagnosis; add'l hour	2002	$21.37	$46.00	$21.09	$19.00
		2003	$21.37	$22.00	$21.09	$19.00
90782	Therapeutic/diagnostic injection; subcutaneous or intramuscular	2002	$4.07	$4.83	$4.18	$2.30
		2003	$4.07	$4.29	$4.28	$2.30
96408	Chemotherapy admin., push technique	2002	$36.97	N/A	$35.86	$30.00
		2003	N/A	$19.00	N/A	$30.00
96410	Chemotherapy admin., infusion; first hour	2002	$58.61	$62.00	$48.00	$52.00
		2003	$58.61	$48.42	$48.00	$52.00
96412	Chemotherapy admin., infusion; add'l hour	2002	$43.85	$69.83	$48.00	$47.00
		2003	$43.85	$44.00	$48.00	$47.00

Not only were these amounts insufficient to cover my expenses in connection with performing the administration services, oftentimes I received no compensation for certain services. For example, prior to 2005, the Medicare rules for drug administration did not take into consideration the extra expenses associated with the provision of drug regimens composed of multiple chemotherapy agents in one session. Under CPT Code 96408, my office was paid for only one push administration per day for a patient regardless of the number of chemotherapy drugs actually administered to the patient by push that day. Similarly, if the infusion of saline, an antiemetic, or any other supportive care drug (normally reimbursed under CPT Codes 90780 and 90781) was administered concurrently with the chemotherapy infusion (CPT Codes 96410, 96412, or 96414), the infusion under CPT Codes 90780 or 90781 was disallowed.

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drugs are injected directly into the bloodstream (intravenous injection) providing the most direct route for the systemic administration of the drug. Finally some drugs are injected directly into the blood supply of a specific organ, e.g., the liver or the brain, (intra-arterial injection) to assay the effects of the drug upon that organ. An IV push describes the administration of a "bolus" (a large dose of drug) into a vein with a syringe by a nurse or physician who must apply pressure to the syringe in order to "push" the medication into the vein. An infusion is when the drug is diluted in a bag of fluids and administered over a specified period of time. It may be "dripped" or administered with a pump. The infusion method requires more elaborate preparation, such as pre-mixing and measurement, whereas an injection or push requires filling a syringe with medication.

In 2004 and 2005, the amounts allowed by Medicare and the private payors for the drug administration codes my office utilized most frequently were as follows:

Code	Description	Year	Medicare	Aetna	Health Partners of Philadelphia	Independence Blue Cross
90780	IV infusion for therapy/ diagnosis; up to one hour	2004	$122.65	$45.00	$31.71	$46.00
		2005		$45.00	$31.71	$46.00
G0347	IV infusion for therapy/ diagnosis; up to one hour	2005	$82.79			
90781	IV infusion therapy/ diagnosis; add'l hour	2004	$34.29	$23.00	N/A	$40.00
		2005		$23.00	$31.71	$39.00
G0348	IV infusion therapy/ diagnosis; add'l hour	2005	$27.60			
G0349	IV infusion therapy/ diagnosis; add'l drug	2005	$45.48			
90782	Therapeutic/diagnostic injection; subcutaneous or intramuscular	2004	$25.16	N/A	$4.28	$3.80
		2005		$4.74	N/A	$3.10
G0351	Therapeutic/diagnostic injection	2005	$19.57			
96408	Chemotherapy admin., push technique	2004	$116.00	$40.00	$9.52	$36.00
		2005		$40.00	$9.52	$36.00
G0357	Chemotherapy admin., push technique	2005	$131.05			
G0358	Chemotherapy admin., push technique; add'l drug	2005	$76.21			
96410	Chemotherapy admin., infusion; first hour	2004	$226.08	$63.00	$58.60	$87.00
		2005		$63.00	$58.60	$87.00
G0359	Chemotherapy admin., infusion; first hour	2005	$185.31			
96412	Chemotherapy admin., infusion; add'l hour	2004	$50.56	$47.00	$58.60	$54.00
		2005		$47.00	$58.60	$54.00
G0360	Chemotherapy admin., infusion; add'l hour	2005	$42.13			

While private payors increased reimbursement for drug administration reimbursement slightly in 2004, Medicare significantly increased its reimbursement for drug administration. For example, by looking at the previous chart, one can see that Medicare reimbursement for CPT Code 90780—infusion of saline, an antiemetic, or any other supportive care drug—increased 187% from $42.72 in 2003 to $122.65 in 2004. Medicare reimbursement for CPT Code 96410—chemotherapy infusion—increased 286% from $58.61 in 2003 to $226.08 in 2004.

In 2005, the drug administration reimbursement for Medicare was higher than 2002 and 2003 but less than 2004. For example, Medicare reimbursement for CPT Code 90780 (replaced by G0347 in 2005) increased 94% from $42.72 in 2003 to $82.79 in 2005. Medicare reimbursement for CPT Code 96410 (replaced by G0359) increased 216% from $58.61 in 2003 to $185.31 in 2005. Although Medicare reimbursement for drug administration was lower in 2005 than in 2004, Medicare added new temporary drug administration codes that allowed my practice to bill for infusion of additional supportive care drugs (G0349) and for administration of additional chemotherapy drugs by IV push (G0358). These new codes better reflect the chemotherapy administration expenses my practice incurs in providing chemotherapy treatment to my patients. Because these G codes were temporary one year codes, the private payors did not switch to G codes. Private payors continued using the old CPT codes in 2005.

While these additional G codes are an improvement over the old drug administration codes, Medicare still does not reimburse for all chemotherapy administration services. For instance, it remains the case that if a patient is infused with saline concurrent with infusion of a chemotherapy agent, the hydration cannot be billed separately. If hydration is provided to facilitate drug delivery, it is considered incidental to that infusion and also cannot be billed separately. In addition, my office still cannot bill separately for flushing a patient's vascular access port prior to the administration of the chemotherapy agent.[9] Medicare and private payors consider it part and parcel of the chemotherapy administration.

As the above suggests, billing for drug administration is highly complex and requires both time and expertise on the part of my nurses and office staff that is not adequately accounted for in the reimbursement for the services themselves. My nurses must keep track of the various drug administrations and the time each takes and must properly document this information. My biller must translate this "real-world" information into the Byzantine coding jargon of the payors. Any errors in either the

[9] A vascular access port is inserted in about 30% of my patients to provide for better access of the patient's vein for drug administration. These patients need a vascular access port either because they have small veins, need repeated frequent chemotherapy administration, or experience a burning sensation when a chemotherapy drug is administered directly in their veins.

recording of what transpired with the patients or in the bills sent to the payors causes a delay if not a denial in the reimbursement I receive, leaving me uncompensated. Moreover, on occasion, the Medicare carrier and the private payors also make errors on their end and my office must follow-up with payors to get properly reimbursed.

50. *J-Codes*: My office bills Medicare and the health plans for drugs administered to patients using J-Codes. J-Codes describe the molecule and the dosage amount. For a few drugs, the J-Code will correspond directly to a National Drug Code ("NDC") number that would provide an informed reader with the name of the drug's manufacturer, the drug's strength and the package size that it comes in. This will hold either because the drug is so new that it has been assigned its own temporary J-Code or because, during the time it remains on patent, there is no other therapeutic or generic competition. However, many of the drugs I prescribe for patients do have therapeutic or generic competition. All such drugs are grouped under one J-Code regardless of the identity of the manufacturer. For example, the J-Code for carboplatin 50 mg is J9045. Regardless of whether I use Paraplatin, the innovator, brand name drug by Bristol-Myers Squibb Company, or a generic carboplatin manufactured by another company, my office bills that drug as J9045. The only way to know which manufacturer's drug was actually administered to a patient would be to look at what was in my inventory at that time.

I do not know precisely how Medicare established the amounts it was willing to reimburse for a J-Code drug. I do know that the methodology was, prior to 2005, based in part on Average Wholesale Price or AWP. I also understand that several of my private payors used either the Medicare J-Code amounts or some formula based in part on AWP to reimburse me for the drugs that I provided to their insureds. In many cases (but not all), I was able to acquire drugs for my inventory at prices less than the amounts at which I was reimbursed. This difference between my acquisition cost and the price that I was reimbursed was income for my practice. This drug income was absolutely essential to make up for (1) drug-related expenditures (such as financing, storage, mixing, waste) that were not separately billable, (2) the under-reimbursed and totally unreimbursed services, facilities and supplies I provided through my office and (3) instances where insurers or patients failed to pay me. Without the drug income, it would

not have been financially worthwhile for me to have maintained my office-based practice.

I generally acquire drugs through OTN, a specialty distributor. As a member of a group purchasing organization called Pennsylvania Oncology Hematology Managers Society (POHMS), I am able to obtain from OTN more favorable prices for drugs and supplies than I could obtain on my own. To run my practice, I must keep a certain amount of drugs in inventory. This is very expensive because I must pay OTN within 10 days, but I generally am not reimbursed for 45 days, at least. I have to absorb the cost of financing this inventory, which because of the expense of these drugs is considerable. My average monthly spending on drugs purchased from OTN ranged from $59,778 to $153,016 between 2002-2005. In addition, some of the drugs have special storage requirements (such as refrigeration) that I must pay for.

When a patient arrives in my office for drug administration, the prescribed drugs are taken from inventory and are prepared. As noted above, this usually involves mixing toxic substances under a laminar flow hood. There is no CPT Code that covered this service, nor was I separately reimbursed for the building space or the environmental controls I must maintain to provide the service.

Finally, to administer the drug, my office uses gowns, gloves, tubes, needles, gauze, tape and other supplies. None of these indirect costs is separately reimbursed under the CPT Codes; the only way for me to recoup these expenses is as part of the drug reimbursement itself.

Coverage Denials and Patient Co-Payments

51. Medicare Part B patients pay an annual deductible and 20% of the allowed charges for physician services and drugs. The patient is responsible for 20% of the allowed charge for the office visit, administration of drugs, and the drugs. For a patient with private health insurance, the co-pay due for the office visit, administration of drugs and drugs is usually a flat amount negotiated between the insurer and the patient's plan sponsor.

52. It is important to stress that, even when a patient has Medicare or private insurance and my office does its level best in terms of the complex coding and billing for a patient's treatment, I sometimes lose a substantial amount of money because (1) Medicare or the private payor denies a claim in part or in full and/or (2) I am unable to collect a co-payment owed by the patient. The staff must approach patients at the front desk when they arrive to the scheduled appointment to confirm that the appropriate referral has been obtained and to collect the copayments.

For example, if I want to give my patient an expensive single-source drug because that drug is the best for that patient based on his cancer and overall medical condition, I request my biller to call the health plan to see if the plan will reimburse me at all. Even when I am assured by the payor that an expensive drug will be reimbursed, the claim still may later be denied. I then have to appeal several times with the health plan. If the appeals fails – which happens on occasion – I can lose thousands of dollars for the drug and for the time and effort in pursuing the denial and appeal.

53. This section has attempted to present the reader with a general description of the economics of my practice. In the following section, I use my practice's financial records to display and analyze the revenues and expenses for 2002 and 2003, which are reflective of the methodology prior to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("Medicare Modernization Act") of using drug revenues through AWP-based reimbursement to subsidize the unreimbursed and under-reimbursed aspects of office-based medical oncology. Thus far, of the payors I work with, only Medicare has moved away from that reimbursement system. 2004 was a "transition" year under the Medicare Modernization Act. In 2005, Medicare reduced the revenues on drugs by reimbursing drugs at ASP +6 %, implemented a "demonstration" project, and increased the payments for office visits under certain CPT Codes and administration of drugs under the new G Codes. I use my practice's financial records to illustrate the effect of the changes in 2004 and 2005.

VI. ECONOMICS OF MY OFFICE PRACTICE: 2002-2005

54. In my office, there are two primary sources of data concerning the revenue and expenses of my practice. The first is "Explanation of Benefit" forms ("EOBs") from Medicare and private payors, which accompany reimbursement checks and describe in detail the revenue that my practice receives.[10] The second source is data from a simple commercially available software program called "Quickbooks," which is used in my office to track revenue and expenses. Sometimes, I retain the actual "hardcopy" of statements or invoices that reflect my expenses, but I believe that Quickbooks is more complete. I routinely purchase drugs and certain other supplies through OTN. Because OTN is a defendant in this case, it was willing to search its own records for a history of my purchases. The OTN data is more complete than my own records and the financial analysis in this section of my affidavit relies on the OTN data whenever possible.

55. At the request of defendants BMS and OTN, I have turned over my EOBs, Quickbooks data, hardcopy invoices and OTN data for the years 2002-2005 (inclusive) to employees of CRA International ("CRA"), whom I understand also to be an expert witness upon whom the Track 1 defendants are relying. I have made myself and my office staff available to CRA staff to answer questions they may have about the information. CRA, not I, created the exhibits that follow concerning the finances of my practice based on the above information. However, I have reviewed the exhibits thoroughly and, based on my own first-hand experience in running my practice, I believe that the results accurately reflect my revenue and expenses and my income and losses. In my discussion below, I elaborate on CRA's findings, especially those concerning the relationship over time between revenues/expenses related to the drugs I prescribe versus the revenues/expenses related to all other parts of my practice. I conclude that the income from the drugs has historically subsidized losses on my services and other expenses.

[10] An Explanation of Benefits (EOB) is a notification form that a health plan sends my office and the patient after processing the claims my office billed. This form includes the services and drugs billed by my office, the amounts allowed and paid, the patient's deductible, and the patient's copayment amount owed to my office.

56. Below, at Exhibit 1, is CRA's analysis of my practice's financial records from 2002-2005. For 2005, CRA analyzed only the revenues and expenses from January through September because not all of the information for the last months of 2005 when CRA did its analysis. However, CRA has extrapolated and computed the last quarter based on the first three quarters' results in order to permit a comparison of all years from 2002 to 2005 on an annualized basis.

57. Among the payors with whom I worked in the period under analysis, only Medicare has switched from a reimbursement mechanism for drugs based on AWP to one based on ASPs. As I discuss below, the impact of this change is clear: I am no longer making significant margins under Medicare on most drugs and, in fact, I am in some cases losing money providing Medicare patients with new classes of drugs. The effect on my practice has been somewhat ameliorated by the fact that I have a fairly low number of Medicare patients as a percentage of the total patient/payor mix.

Exhibit 1

Physician Oncology, LTD

2002-2005 Income Statements, Accrual Method
By Source of Payment (Third-Party Payor and Patient)

	Revenues	2002 [a]	2003 [b]	2004 [c]	2005 [d]
	Amount Paid by Public and Private Third-Party Payors				
[1]	Amount Paid for Drugs	$911,685	$867,086	$1,178,330	$2,242,267
[2]	Amount Paid for Services	$276,974	$218,092	$438,885	$442,000
[3]	Amount Paid for Oncology Demonstration Project	$0	$0	$0	$18,231
	Other Amounts Paid	$54,622	$56,318	$49,883	$34,208
	Total Revenue from Third-Party Payors	$1,243,281	$1,141,497	$1,667,098	$2,736,707
	Amount Designated as Due from Patients				
	Gross Revenue Due from Patients	$227,692	$53,565	$188,763	$123,550
	Uncollected Patient Obligations	($215,882)	($36,470)	($175,607)	($102,184)
	Total Net Revenue from Patients	$11,810	$17,095	$13,156	$21,366
	Total Net Revenue	**$1,255,091**	**$1,158,592**	**$1,680,254**	**$2,758,073**
	Costs and Expenses				
	OTN Drug Purchases	$730,014	$842,302	$989,301	$1,947,768
	Rebates and Discounts	($12,681)	($2,819)	($20,204)	($111,571)
[4]	Medical Supplies	$24,517	$20,424	$20,674	$25,973
	Office Supplies	$12,718	$11,739	$7,309	$16,093
	Payroll and Payroll Taxes excluding physician's salary	$164,975	$148,574	$136,246	$233,976
	Employee Health Insurance	$7,296	$2,153	$12,149	$30,533
	Rent	$38,354	$58,425	$76,073	$68,588
[5]	Other	$90,732	$111,103	$135,315	$130,286
	Total Costs and Expenses	**$1,055,924**	**$1,191,899**	**$1,356,862**	**$2,341,647**
	Net Income (Including Physician's Salary)	**$199,166**	**($33,307)**	**$323,392**	**$416,426**

[1] EOB payments received from third-party payors for HCPCS J-Codes, Q0136, S5000, S5001, and S0023
[2] EOB payments for all Service-Related billing codes
[3] EOB payments received from third-party payors, including Medigap, for Oncology Demonstration Project Codes
[4] [a] Medical Supply expenses as recorded on Dr. Linda Haegele's QuickBooks accounts
[4] [b-d] Medical Supply expenses paid to specifically identified suppliers other than OTN as recorded on Dr. Linda Haegele's QuickBooks accounts plus OTN purchases of medical supplies
[5] Expenses categorized as advertising and promotion, amortization, automobile, bank fees, charity, depreciation, dues and licenses, entertainment, gifts, malpractice insurance, group and liability insurance, interest, legal, meetings and education, miscellaneous, outside services, patient relations, payroll service fees, postage, professional fees, refunds, repairs and maintenance, subscriptions and books, other taxes, telephone, travel, uniforms, utilities, and waste removal expenses per QuickBooks accounts
[d] Annualized based on data from the first three quarters of 2005

58. CRA created the income statements in Exhibit 1 by analyzing the revenues (a) from payors for (i) drugs and (ii) services (i.e. office visits, lab work and administration of services) and (b) the amounts due from patients (without a breakdown as between drugs and services). The total revenues were adjusted to reflect the write-off of the uncollected patient co-pays, which were quite substantial. Losses due to drug coverage denial by payors are reflected as an expense (for my purchase of the drug) without any offsetting revenue (since the EOB would reflect no payment for the drug by the payor).[11] CRA also analyzed the expenses incurred by my practice including OTN

[11] My practice incurred bad debt for several reasons. Sometimes, I and my staff were unable to collect the co-pay from patients. Other times, my practice treated patients who appeared to have insurance coverage,

drug purchases (less drug rebates and discounts), medical supplies, office supplies, staff payroll and payroll taxes, employee health insurance, rent and other expenses. These other expenses include advertising and promotion, amortization, automobile, bank fees, charity, depreciation, dues and licenses, professional fees, entertainment, gifts, malpractice insurance, group and liability insurance, interest, meetings and education, payroll service fees, postage, refunds, repairs and maintenance, subscriptions and books, telephone, travel, uniforms, utilities, waste removal expenses and taxes.

59. As one can see from Exhibit 1, my net income during the course of the year has ranged from $200,000 to $416,000 per year, with one year (2003) reflecting a loss. I believe that these amounts are on the low end of the range for medical oncologists in the Greater Philadelphia area and are very low compared to other private-sector professionals given the relative time, expense and effort I put into my education, training and day-to-day practice. My income reflects my personal commitment to serving people from all walks of life.

60. Uncollected patient obligations are a significant drain on my practice, although I cannot blame my loss in 2003 entirely on that issue. For example, in 2002, my practice wrote off $215,882 in bad debt as a result of uncollected patient copays, lapsed coverage, and drug coverage denial. $161,135 was attributable to one patient. His health plan denied coverage of an expensive drug that I administered to him despite what I believe was a prior approval by the plan. The patient passed away in late 2002 and I never was able to collect the debt. It should be noted that some of the bad debt in 2005 resulted from my decision not to ask my patients for co-payments relating to Medicare's "oncology demonstration project." I felt it was hard enough for my patients to pay their share of services and drugs without adding to their financial burden by asking for a co-pay on the demonstration projection. [12]

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but whose coverage had in fact lapsed and whose claims were denied by the insurance companies on that basis. Finally, as I noted above, some insurers have denied coverage for some drugs even after my practice had been told orally, in a prior-authorization phone call, that the drugs would be covered by them.

[12] The oncology demonstration project focused on three areas of concern often raised by patients undergoing chemotherapy: controlling pain; minimizing nausea and vomiting; and reducing fatigue. To

61. I lost money in 2003 primarily because I had an inexperienced biller. Exhibit 1 shows that while my drug expenses increased from 2002 to 2003, I received much less revenue from third-party payors and, particularly, from patients. My biller also did not call the health plans to see if the patients had current insurance coverage before we treated them. As a result, I treated a number of patients who had no insurance. My biller also failed to follow up on denials of claim when there was coverage. In many cases, my office did not even try to obtain payment from the patients, thus explaining why both the gross revenue due from patients and uncollected patient obligations are so low for 2003.

62. Exhibit 1 also shows that in every year from 2002 to 2005, the revenue that I received from payors relating to the drugs I administer is much higher as a percentage of total revenue than the revenue I receive from services. This is especially true in the period 2002-2003 – before the effect of the Medicare Modernization Act. The relationship between drug and other revenues started to change beginning in 2004.[13] I explore this change further in Exhibit 2 below.

63. Exhibit 2 contains the exact same raw data as Exhibit 1, but allocates expenses related to drug revenues separately from expenses related to services revenue in order to show my practice's operating profit (or loss) from drugs versus services. CRA calculated the drug revenues by analyzing the amount reimbursed by Medicare and private payors for the drugs plus the amount of co-pay for the drug due from the patient

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participate in the demonstration project, the nurse fills out a questionnaire that asks the Medicare patient questions about his or her symptoms and quality of life during the course of chemotherapy administration. My practice is reimbursed $130 per Medicare patient per encounter for participating in the nationwide demonstration project. The oncology demonstration project can only be billed in conjunction with either G0357 (chemotherapy administered through intravenous push) or G0359 (chemotherapy administered through infusion).

[13] For 2002 and 2003, Medicare set drug reimbursement at the lower of the billed charge for a drug or 95% of a drug's AWP. In 2004, Medicare increased its payments for office visits and drug administration services and decreased payments for drugs by reimbursing at 85% of a drug's AWP (as of April 1, 2003) or 95% of a new drug's AWP. A new drug is defined as an unlisted drug, not covered by a HCPCS code, that was FDA-approved after April 1, 2003.

minus the cost of my drug purchases from OTN (accounting for any rebates or discounts I received) and minus the bad debt written off as a result of uncollected patient drug co-pays. Even with the bad debt and denials by payors, I have in every year operated at a profit on the drugs themselves.

64. CRA analyzed the service revenues from office visits, lab work and drug administration by determining the amount reimbursed by Medicare and private payors and patient co-pays less all expenses not included in the drug expenses: medical supplies, office supplies, staff payroll expenses, staff health insurance, rent, and other expenses described above. I broke even or lost money on the "services" side of my practice in 2002 and 2003 (before the Medicare Modernization Act) and only made money once Medicare began changing the reimbursement for services in 2004. I would also have done well on services in 2005 had I not experienced a large increase in the payroll and payroll taxes relative to 2004. My payroll and taxes went up because my per diem nurses worked more hours, I employed a full-time biller for the entire year and I retained a consultant to help me with my practice management.

Exhibit 2

Physician Oncology, LTD

2002-2005 Income Statements, Accrual Method

By Source of Revenue (Drug Revenue versus Procedure Revenue)

		2002	2003	2004	2005
[1]	**Drug Revenue**	[a]	[b]	[c]	[d]
	Amount Paid by Third-Party Payors for Drugs	$911,685	$867,086	$1,178,330	$2,242,267
	Amount Due from Patients for Drugs less Medigap payments	$189,673	$16,697	$112,944	$59,428
[2]	Patient Obligation 'Write-Offs' of Drug Revenue	($189,673)	($16,697)	($112,944)	($59,428)
	Total Net Revenue from Drugs	$911,685	$867,086	$1,178,330	$2,242,267
	OTN Drug Purchases	$730,014	$842,302	$989,301	$1,947,768
	Rebates and Discounts	($12,681)	($2,819)	($20,204)	($111,571)
	Total Net Drug-Related Costs	$717,334	$839,482	$969,096	$1,836,197
	Operating Profit from Drugs	**$194,351**	**$27,604**	**$209,234**	**$406,070**
	Operating Margin from Drugs	**21.3%**	**3.2%**	**17.8%**	**18.1%**
[3]	**Service-Related, Oncology Demonstration Project, and Other Revenue**				
	Amount Paid by Third-Party Payors for Services	$276,974	$218,092	$438,885	$442,000
	Amount Due from Patients for Services less Medigap payments	$35,441	$29,903	$73,689	$62,300
	Other Amounts Due from Patients less Medigap payments	$2,578	$6,965	$2,130	$651
	Amount Due from Patients for Demonstration Project less Medigap payments	$0	$0	$0	$1,171
	Amount Paid by Medicare for Demonstration Project	$0	$0	$0	$18,231
	Other Amounts Paid by Third-Party Payors	$54,622	$56,318	$49,883	$34,208
[4]	Patient Obligation 'Write-Offs' of Service-Related, Demonstration Project, and Other Revenue	($26,210)	($19,773)	($62,663)	($42,756)
	Total Net Service-Related, Oncology Demonstration Project, and Other Revenue	$343,406	$291,505	$501,924	$515,805
	Expenses				
[5]	Medical Supplies	$24,517	$20,424	$20,674	$25,973
	Office Supplies	$12,718	$11,739	$7,309	$16,093
	Payroll and Payroll Taxes excluding physician's salary	$164,975	$148,574	$136,246	$233,976
	Employee Health Insurance	$7,296	$2,153	$12,149	$30,533
	Rent	$38,354	$58,425	$76,073	$68,588
[6]	Other	$90,732	$111,103	$135,315	$130,286
	Total Service-Related and Other Expenses	$338,591	$352,417	$387,766	$505,449
	Operating Profit from Service-Related, Demonstration Project, and Other Revenue	**$4,815**	**($60,911)**	**$114,158**	**$10,356**
	Operating Margin from Service-Related, Demonstration Project, and Other Revenue	**1.4%**	**-20.9%**	**22.7%**	**2.0%**
	Net Income (Including Physician's Salary)	**$199,166**	**($33,307)**	**$323,392**	**$416,426**
	Total Operating Margin	**15.9%**	**-2.9%**	**19.2%**	**15.1%**

[1] EOB revenue from HCPCS J-Codes, Q0136, S5000, S5001, and S0023

[2] Amounts due from patients for Drugs less allocated amounts paid by patients and Medigap plans

[3] EOB revenue from Service-Related, Oncology Demonstration Project, and Other billing codes

[4] Amounts due from patients for Service-Related, Oncology Demonstration Project, and Other billing codes less allocated amounts paid by patients and Medigap plans

[5] [a] Medical Supply expenses as recorded on Dr. Linda Haegele's QuickBooks accounts

[5] [b-d] Medical Supply expenses paid to specifically identified suppliers other than OTN as recorded on Dr. Linda Haegele's QuickBooks accounts plus OTN purchases of medical supplies

[6] Expenses categorized as advertising and promotion, amortization, automobile, bank fees, charity, depreciation, dues and licenses, entertainment, equipment rentals, gifts, malpractice insurance, group and liability insurance, interest, legal, meetings and education, miscellaneous, outside services, patient relations, payroll service fees, postage, professional fees, refunds, repairs and maintenance, subscriptions and books, other taxes, telephone, travel, uniforms, utilities, and waste removal expenses per QuickBooks accounts

[d] Annualized based on data from the first three quarters of 2005

65. There were other important changes to my practice from 2004 to 2005. First, both my drug revenues and expenses increased dramatically compared to prior years. As I explain more fully below, this is in part because of the availability of new and improved drugs with which to treat cancer. Second, as already noted, in 2005, Medicare began reimbursing for drugs based on ASP + 6%. Fortunately, none of the private payors with whom I worked followed Medicare's lead. Americhoice and Aetna US Healthcare

reimbursed drugs at 85% of AWP. Independent Blue Cross reimbursed at 90% of AWP. Health Partners of Philadelphia reimbursed at 85% of AWP. After discussing the reasons for the changes in my drug prescribing patterns, I will attempt to demonstrate for the reader the implications for patient care in Medicare's change to an ASP reimbursement methodology. In brief, I am making less – and in some cases losing money – on the drugs that I administer to Medicare patients.

66. Some of the relatively new drugs that I have begun to use include Avastin, Herceptin and Erbitux. These drugs are part of what is referred to as "targeted therapies." In the past, many cytotoxic chemotherapy drugs indiscriminately killed not only cancer cells but also rapidly dividing normal cells such as bone marrow, causing side-effects like neutropenia. These new drugs differ from the older cytotoxic drugs because they are developed utilizing the biochemistry of the tumor. Because tumors produce certain proteins that normal cells do not have, the drug can target and attack the cancer cells without damaging normal cells. This leads to fewer adverse side-effects for patients. These drugs are expensive because of the high research and development costs and extensive clinical trials. While I believe that these new drugs are better for my patients than some of the older drugs, I make sure I get pre-certification because I cannot afford to have a claim denied.

67. During 2005, I also made a shift in the erythropoietin that I prescribed for many of my patients from Procrit to Aranesp.[14] In my professional opinion Aranesp is equally effective as Procrit, but Aranesp saves me and my patients time. Moreover, it was not financially feasible for me to provide Procit to Medicare patients in 2005 because the Medicare reimbursement did not cover my acquisition cost. My practice lost $71.53 per shot of Procrit administered to Medicare patients.

68. Beginning in 2005, I started prescribing many patients Neulasta instead of Neupogen. Both drugs are colony-stimulating growth factors that stimulate the bone

[14] Erythropoietin, a growth factor, is administered to increase a patient's red blood count during the course of chemotherapy treatment.

marrow to make white blood cells to fight chemotherapy-induced neutropenia. In my opinion, Neulasta is as effective as Neupogen, but is much more convenient for my patients than Neupogen. While Neupogen must be administered daily, Neulasta may be administered as a single dose per chemotherapy cycle. This results in fewer injections and fewer office visits for my patients.

69. Below, Exhibit 3 shows the margins I received on all drugs administered to Medicare patients in both 2004 and 2005. Significantly, Medicare's reimbursement of 85% of AWP in 2004 did not cover my acquisition cost for the following drugs: Zometa, fluorouracil, RituXan, Herceptin, and Faslodex. In other words, I lost money on these drugs when I prescribed them for my Medicare patients. Unfortunately, Medicare's switch to a reimbursement of ASP + 6% in 2005 exacerbated the problem. In 2005, the Medicare reimbursement for almost half of the drugs I prescribed did not compensate me fully for the drugs' acquisition cost. I was unable to recover the cost of the following drugs: leucovorin calcium, diphenhydramine HCL, normal saline solution, cyclophosphamide, fluorouracil, RituXan, Herceptin, Faslodex, and Procrit. I do not believe that I will be able to continue to afford providing the best drugs to my Medicare patients unless Medicare significantly improves the compensation for my services and practice expenses.

Exhibit 3
Physician Oncology, LTD
Medicare Drug Margins, 2004 - 2005

2004 - 2005 Summary

Drug Name	HCPCS Code	2004 Net Cost per Billing Unit	2004 Medicare Reimbursement Amount	2004 Gross Margin (%) [1]	2005 Net Cost per Billing Unit	2005 Medicare Reimbursement Amount	2005 Gross Margin (%) [1]	Change in Gross Margin %
Leucovorin calcium	J0640	$1.18	$2.85	58.5%	$2.09	$1.21	-72.6%	-131.2%
Darbepoetin alfa (Aranesp)	J0880	$18.01	$20.14	10.6%	$14.24	$15.31	7.0%	-3.6%
Dexamethasone sodium phosphate	J1100	$0.06	$0.10	44.0%	$0.06	$0.14	60.1%	16.1%
Diphenhydramine HCl	J1200	$0.98	$1.36	27.8%	$0.99	$0.55	-80.0%	-107.9%
Dolasetron mesylate (Anzemet)	J1260	$5.03	$13.16	61.8%	$3.98	$6.11	34.8%	-27.0%
Pamidronate disodium	J2430	$71.15	$225.99	68.5%	$51.98	$54.48	4.6%	-63.9%
Pegfilgrastim (Neulasta)	J2505	$2,259.24	$2,382.13	5.2%	$1,929.62	$2,160.23	10.7%	5.5%
Zoledronic acid (Zometa)	J3487	$189.20	$184.81	-2.4%	$187.94	$188.78	0.4%	2.8%
Normal saline solution	J7050	$0.89	$2.11	57.6%	$0.93	$0.24	-296.2%	-353.8%
Carboplatin	J9045	$87.84	$128.39	31.6%	$14.44	$119.20	87.9%	56.3%
Cyclophosphamide	J9070	$2.11	$4.87	56.8%	$1.81	$1.81	-0.1%	-56.8%
Docetaxel (Taxotere)	J9170	$278.64	$286.33	2.7%	$268.18	$280.91	4.5%	1.8%
Fluorouracil	J9190	$1.85	$1.76	-5.1%	$1.81	$1.76	-3.1%	1.9%
Methotrexate sodium	J9260	$2.11	$4.04	47.7%	$2.11	$2.53	16.4%	-31.3%
Rituximab (RituXan)	J9310	$430.02	$416.46	-3.3%	$437.38	$433.12	-1.0%	2.3%
Trastuzumab (Herceptin)	J9355	$50.50	$49.41	-2.2%	$52.21	$50.34	-3.7%	-1.5%
Vinorelbine tartrate	J9390	$43.17	$72.38	40.4%	$34.03	$58.61	41.9%	1.6%
Fluvestrant (Faslodex)	J9395	$78.62	$77.49	-1.5%	$79.05	$77.32	-2.2%	-0.8%
Epoetin alfa (Procrit)	Q0136	$8.61	$11.04	22.0%	$11.10	$9.32	-19.2%	-41.2%

1: Gross Margin (%) equals Reimbursement Amount minus Net Cost per Billing Unit divided by Reimbursement Amount.
2: Excludes losses on refunds for returned Epoetin alfa in 2005

70. The problem is even more acute for an oncologist with a higher percentage Medicare patient mix than mine. While I have a Medicare Part B patient mix of 15-20%, many medical oncology practices have a Medicare patient mix of 50%. The data suggest such office-based oncologists would not be able to treat their Medicare Part B patients without significant increases in reimbursements for services.

LINDA A. HAEGELE, M.D.

Sworn to before me this
16 day of November, 2006

Notary Public

Appendix A

CURRICULUM VITAE

LINDA A. HAEGELE, M.D.

Date of Birth:	July 1, 1946 Abington, PA
Husband:	Emanuel Rubin, M.D.
Children:	Ariel D. Rubin Ethan B. Rubin
Residence:	1505 Monk Road Gladwyne, PA 19035
Education:	
College:	Temple University College of Liberal Arts Philadelphia, PA A.B.- Magna Cum Laude 1964-1968
Research Associate:	Department of Biochemistry Temple University School of Medicine Philadelphia, PA 1968-1969
Medical School:	Temple University School of Medicine Philadelphia, PA 1969-1973
Internship:	Internal Medicine Albert Einstein Medical Center Northern Division Philadelphia, PA 1973-1974
Residency:	Internal Medicine Albert Einstein Medical Center Northern Division Philadelphia, PA 1974-1976
Fellowship:	Fellow in Hematology/Medical Oncology Hahnemann University Hospital Philadelphia, PA 1976-1979

Degrees: A.B. , M.D.
Diplomate, American Board of Internal Medicine

Licensure: Pennsylvania Medical License

Practice: Private Practice Hematology and Medical Oncology
March 1979-July 1997
Physician Oncology Specialists, Inc.
July 1997- June 1999
Physician Oncology, Ltd.
July 1999- Present

Academic Activities:

Hahnemann University School of Medicine
Philadelphia, Pa
Instructor in Hematology Oncology
1978-1979
Course Director in Hematology School of Allied Health Profession
1978-1979

Philadelphia College of Osteopathic Medicine
Philadelphia, PA
Chairman, Division of Hematology and Medical Oncology
1990-2002
Professor, Department of Medicine
1990-2002

Course Co-Director:
Second Year Student Course-
Interdisciplinary Oncology-until 2002

Third Year Student Clinical Course-
Hematology/ Medical Oncology- until 2002

Jefferson Medical College
Philadelphia, PA
Clinical Assistant Professor of Medicine
1995- Present

Hospital Affiliations and Appointments:

Active Staff:

Tenet- Parkview Hospital
1331 E. Wyoming Avenue
Philadelphia, PA 19124
1990- 2003

Chairman, Division of Hematology and Medical Oncology
1980- 2003

Tumor Committee
Member: 1979- 1982
Chairman 1982- 2003

Transfusion Committee:
Member: 1980-1982
Chairman: 1982-1994
Member: 1994-2000

Formulary Committee
1985-2000

Radiation Safety Committee
1985-2000

Director, Outpatient Infusion Unit
1980-1997

Cancer Support Group
Medical Oncology Advisor
1980-1997

Medical Education Committee
1991-2000

Albert Einstein Medical Center
Northern Division
Old York and Tabor Roads
Philadelphia, PA 19141
1980- Present

Temple University
Northeastern Hospital
2301 E. Allegheny Avenue
Philadelphia, PA 19134
1982- Present

Tissue/ Transfusion Procedure Committee
Chairman: 1991-2002

Cancer Committee
Member: 1991-1997

Nazareth Hospital
2601 Holme Avenue
Philadelphia, PA 19152
1982-Present

Tenet- City Avenue Hospital
4150 City Avenue
Philadelphia, PA 19131
1988-2000

Chairman, Division of Hematology and Medical Oncology
1990-2000

Medical Resident Core Curriculum
Hematology and Medical Oncology
Course Director:
1990-1997

Tumor Committee
Chairman:
1990-1997

Intern Selection Committee
1990-1997

Intern Evaluation Committee
1990-1997

Einstein - Elkins Park Hospital
Moss Rehabilitation
60 E Township Line Road
1982- Present

Episcopal Hospital
Front and Lehigh Streets
Philadelphia, PA 19125

Chairman, Division of Hematology and Medical Oncology
1990-1997

Temple- Jeanes Hospital
7600 Central Avenue
Philadelphia, PA 19111
1980- Present

Thomas Jefferson University Hospital
111 S. 11th Street
Philadelphia, PA 19107
1995- Present

Other Professional Activities:

PA Osteopathic Medical Association
Continuing Medical Education Programs
Lecturer: 1990-2000

Philadelphia College of Osteopathic Workshops
Continuing Medical Education Programs
St. Thomas Review Course
Medical Oncology Program
Lecturer: 1991
Linda Creed Foundation
Breast Cancer Support Services Workshops
Medical Oncology Advisor
1994-2000

Hospice of the Delaware Valley
Medical Oncology Advisor
1994-2000

Compassionate Care Hospice
Medical Director
1999-2001

Societies:

American Medical Association:
1979-1997
Philadelphia County Medical Society:
1979-1997
Pennsylvania State Medical Society:
1979-1997
American College of Physicians:
1979-1997
PA Society of Hematology and Medical Oncology
American Society of Clinical Oncologists

Community Memberships:

Friends of Philadelphia Museum of Art
American Horticultural Society
Philadelphia Orchestra Association
Metropolitan Opera Guild
Philadelphia Zoological Society
Franklin Institute

Publications:

1. Haegele, L.A. : Endocrine Neoplasia in Cancer Chemotherapy III, Eds. Brodsky,I., Kahn, S.B. and Conroy, J.F. Grune and Stratton, New York, 1978.

2. Haegele, L.A. : Fuscaldo, K.E. and Brodsky, I., Clonal evolution and retroviral indicators in lymphoplastic transformations of CML. Abstract American Society of Hematology, December, 1978.

3. Haegele, L.A., Conroy, J.F., Brodsky, I. And Kahn, S.B. : Dimethyl triazene imidazole carboxamide (DTIC) and mitomycin-C in the treatment of advanced colon carcinoma. Abstact American Society of Clinical Oncology, 1979.

4. Haegele, L.A. : " Medical Surveillance of Laboratory Personnel" in Biohazard Safety, Eds. Fuscaldo, A.A. and Erlich, B.J. Academic Press, 1980.

5. Haegele, L.A. Hematology and Oncology, in Schlossberg, D. (ed) Review of Internal Medicine. Lippincott-Raven Philadelphia, 1996.